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YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EXAMINER LARYEA, LAWRENCE N	
			ART UNIT 3768	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,607

Applicant(s)

GENET ET AL.

Examiner

Lawrence N. Laryea

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/18/2005</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

2. The abstract of the disclosure is objected to because of the following informalities:

At page 3, lines 17 and 25 , it is unclear what applicant meant by the limitation "in vivo in situ image"

At page 5, lines 11, it is unclear what applicant meant by the limitation "in vivo in situ image"

Correction is required.

Claim Objections

3. Claims 1-25 are objected to because of the following informalities:

At Claim 1,line 2, At Claim 13, it is unclear what applicant meant by the limitation "in vivo in situ image"

At Claim 14,it is unclear what applicant meant by the limitation "in vivo in situ image" Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 2, the phrase " approximately " renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

6. Claim 1, at lines 4-5 recite the limitation " the point by point scanning " at line 3. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 1, at line 7 recite the limitation " the exit of said fibre". There is insufficient antecedent basis for this limitation in the claim.

8. Claim 1, at line 7 recite the limitation " said bundle ". There is insufficient antecedent basis for this limitation in the claim.

9. Claim 3, at line 7 recite the limitation " the end of the fibres". There is insufficient antecedent basis for this limitation in the claim.

10. Claim 3, at line 8 recite the limitation " the surface". There is insufficient antecedent basis for this limitation in the claim.

11. Claim 3, at line 8 recite the limitation " the surface". There is insufficient antecedent basis for this limitation in the claim.

12. Claim 3, at line 8 recite the limitation " the core diameter". There is insufficient antecedent basis for this limitation in the claim.

13. Claim 5, at lines 4-5 recite the limitation " the whole of the emission band ".

There is insufficient antecedent basis for this limitation in the claim.

14. Claim 7, at lines 3-4 recite the limitation " the placement".

There is insufficient antecedent basis for this limitation in the claim.

15. Claim 8, at lines 2-3 recite the limitation " the real injection rate ".

There is insufficient antecedent basis for this limitation in the claim.

16. Claim 9, at line 2 recites the limitation " the collected flux ".

There is insufficient antecedent basis for this limitation in the claim.

17. Claim 9, at line 2 recites the limitation " the background image ".

There is insufficient antecedent basis for this limitation in the claim.

18. Claim 10, at lines 1-2 recite the limitation " the digitized signal ".

There is insufficient antecedent basis for this limitation in the claim.

19. Claim 10, at lines 1-2 recite the limitation " the digitized signal ".

There is insufficient antecedent basis for this limitation in the claim.

20. Claim 10, at line 3 recites the limitation " the flux".

There is insufficient antecedent basis for this limitation in the claim.

21. Claim 11, at lines 1-2 recite the limitation " the image from the corrected signal ".

There is insufficient antecedent basis for this limitation in the claim.

22. Claim 13, at lines 10-11 recite the limitation " the entry section ".

There is insufficient antecedent basis for this limitation in the claim.

23. Claim 13, at line 17 recite the limitation " the distal end ".

There is insufficient antecedent basis for this limitation in the claim.

24. Claim 13, at line 18 recite the limitation " the observed tissue ".

There is insufficient antecedent basis for this limitation in the claim.

25. Claim 13, at line 25 recite the limitation " the minimum one-by-one fibres".

There is insufficient antecedent basis for this limitation in the claim.

26. Claim 14, at lines 16 recite the limitation " the end of each fibre ".

There is insufficient antecedent basis for this limitation in the claim.

27. Claim 15, at line 17 recite the limitation " the longitudinal monomode type ".

There is insufficient antecedent basis for this limitation in the claim.

28. Claim 16, at line 17 recite the limitation " the section of a fibre ".

There is insufficient antecedent basis for this limitation in the claim.

29. Claim 17, at line 4 recites the limitation "it." This limitation renders the claim indefinite because one cannot be certain what "it" is intended to refer to.

30. Claim 20, at line 4 recites the limitation " the rotation planes ".

There is insufficient antecedent basis for this limitation in the claim.

31. Claim 21, at line 2 recites the limitation " optical means ".

There is insufficient antecedent basis for this limitation in the claim.

32. Claim 21, at line 5 recites the limitation " the photons ".

There is insufficient antecedent basis for this limitation in the claim.

33. Claim 21, at line 5 recites the limitation " the width".

There is insufficient antecedent basis for this limitation in the claim.

34. Claim 21, at line 6 recites the limitation " the spectral band ".

There is insufficient antecedent basis for this limitation in the claim.

35. Claim 22, at line 2 recites the limitation " the optical aberrations ".

There is insufficient antecedent basis for this limitation in the claim.

36. Claim 22, at line 2 recites the limitation " the edge ".

There is insufficient antecedent basis for this limitation in the claim.

37. Claim 22, at line 3 recites the limitation " the field ".

There is insufficient antecedent basis for this limitation in the claim.

38. Claim 22, at line 3 recites the limitation " the actual injection ".

There is insufficient antecedent basis for this limitation in the claim.

39. Claim 24, at line 4 recites the limitation "it." This limitation renders the claim indefinite because one cannot be certain what "it" is intended to refer to.

40. Claim 16, at line 17 recite the limitation " the section of a fibre ".

There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

41. Claims 13-24 and 25 rejected under 35 U.S.C. 101 as being directed to neither a "process" nor a "machine," but rather embracing or overlapping two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. See MPEP § 2173.05(p)(11).
42. Further Claims 13 is rejected under 35 U.S.C. 112, second paragraph, as a single claim which claims both an apparatus and the method steps of using the

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apparatus is indefinite. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph. See MPEP § 2173.05(p)(11).

43. Further Claims 14 is rejected under 35 U.S.C. 112, second paragraph, as a single claim which claims both an apparatus and the method steps of using the apparatus is indefinite. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph. See MPEP § 2173.05(p)(11).

Claim Rejections - 35 USC § 102

44. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

45. Claims 1-25 are rejected under 35 U.S.C. 102(b) as being anticipated by

Richards-Kortum et al (Patent 6370422).

46. Re Claims 1,3,5,7,13,14 and 21: **Richards-Kortum et al** teach an apparatus for in situ and in vivo fibred optic confocal fluorescence imaging (**See Col. 1, lines 16-**

19) comprising: the image guide (**See Col. 4, lines 14-20**); the source (**12**) emitting continuously at the excitation wavelength of at least one targeted fluorophore, means for rapid scanning (**34**) and injection (**36,44 and 46**) fibre by fibre over time of the excitation beam produced by the source by lines and by columns in a XY plane corresponding to the entry section of the image guide (**38**); means (**16**) for separating the excitation wavelength and the fluorescence wavelengths; means for detection (**28**) of the fluorescence signal; and means for processing the detected signal allowing the realization of an image; an optical head (**See Figs3. 23,2,3 and Col. 10 lines 34-40**) being arranged at the distal end, intended to be brought into contact with the observed tissue, allowing the excitation beam to be focussed characterized in that: the scanning means are suitable for moving the excitation beam at a speed corresponding to the obtaining of an image in real time; and the detection means (**Col. 16 lines 53-67; Col. 17 lines 1-67, Col. 18 lines 1-25**) have a pass-band whose frequency is fixed as a function of the minimum one-by-one fibres sampling frequency (**See Col. 3 lines 61-67, Col. 4 lines 38-67, Col. 5 lines 1-34, Col. 11 lines 38-45, Col. 12 lines 65-67, Col. 13 lines 1-56 See Figures 1-31**). See *In Dilnot*, 319 F.2d 188, 138 USPQ 248(CCPA 193).

47. Re Claim 2, **Richards-Kortum et al** teaches that it is required to have a numerical aperture of the focussing optics aperture with a diameter that will be equal to size of the fiber image (**See Col. 10 lines 51-54, Col. 9 lines 49-67**) .

48. Re Claim 4: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein the deflection speed of the excitation beam is adjusted by determining

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a rapid-resonance frequency of a resonating line mirror and a slow-resonance frequency of a galvanometric frame mirror (**See Col. 8, lines 42-44 and Col. 10, lines 26-29**).

49. Re Claim 6: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein a quantum efficiency of detection at the fluorescence wavelengths to be detected of at least 50% (**See Col. 10, lines 49-52**).

50. Re Claim 8: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein determining the real injection rate particular to each fibre (**See Col. 10, lines 55-58**).

51. Re Claims 9 and 10: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein correcting the digitized signal coming from a fibre by subtraction of the flux corresponding to the background image and adaptation to the real rate of injection which is particular to said fibre (**See Col. 13, lines 65-67, Col. 14, lines 54-59, Col. 18, lines 5-15**).

52. Re Claim 11: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein reconstructing the image from the corrected signal and reconstructing the image comprises a Gaussian low-pass filtering. (**See Col. 16, lines 53-67, Col. 17, lines 1-67, (See Col. 17, lines 1-25)**

53. Re Claim 15: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein the excitation beam produced by the source is of the longitudinal monomode type presenting an optimum wave front quality for the injection into a slightly multimode optical fibre (**See Col. 10 lines 4-15 and Col. 14 lines 1-3**).

54. Re Claim 16: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein the section of a fibre being circular, the excitation beam produced by the source is circular so as to optimize the injection into a fibre (**Figures 2,3 and 15**).

55. Re Claim 17: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein means (**54**) for shaping the beam used on the exit of the source in order to shape the excitation beam so as to adapt it to the injection means in the image guide (**See Fig. 3 and 12**).

56. Re Claim 18: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein the means for separating the excitation and fluorescence wavelengths comprise a dichroic filter (**56**) having a maximum efficiency at the excitation wavelength.

57. Re Claim 19: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein rejection means (**30**) placed upstream of the detection means and suitable for eliminating the excitation wavelength.

58. Re Claim 20: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein the scanning means comprise a resonating line mirror, a galvanometric frame mirror, a first afocal optical system with unitary magnification adapted for the conjugation of the two mirrors and a second afocal system with unitary magnification adapted for the conjugation of the rotation planes of the two mirrors with the injection plane in one of the fibres (**See Col. 10 lines 9-33 and Fig. 5**).

59. Re Claim 22: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein the injection means comprise two optical units, the first unit (**46**) being adapted for correcting the optical aberrations at the edge of the field of the scanning

means and the second unit **(44)** being adapted for carrying out the actual injection in one of the fibres of the image guide **(See Figures 2,3,15 and 16-33)**.

60. Re Claim 23: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein the first optical unit **(206)** comprises a doublet and the second optical unit comprises two doublets followed by a lens**(44)**. **(See Fig. 30)**.

61. Re Claim 24: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein a filtering hole **(26)** is placed in front of the detection means **(11)** whose diameter is chosen so that the image of a fibre fits into it **(See Figures 1,2,6A and 6B)**.

62. Re Claim 25: **Richards-Kortum et al** teach a fibred optic confocal fluorescence imaging wherein means **(66)** for focussing the fluorescence signal on the filtering hole **(See Fig.5)**.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Smid (Patent 5450501) teaches an imaging system for point by point scanning of an object.

Tearney et al (Patent 7231243), Rosenberg (Patent 6753966), Benaron et al (Patent 6748259), Modell et al (Patent 6748259), Freitag et al (Patent 6061591) and Lauer (2004/0032650) teach a optical imaging system for diagnosing tissue by fluorescence observation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lawrence N. Laryea whose telephone number is 571-272-9060. The examiner can normally be reached on 9:30 a.m.-5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LNL

A handwritten signature in black ink, appearing to read 'B. Casler', positioned above the printed name.

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700